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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,350	10/11/2001	Martin J. Jacobs	CP215	9510

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CEPHALON, INC.
41 MOORES ROAD
PO BOX 4011
FRAZER, PA 19355

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/975,350	JACOBS ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8-50,55-61 and 63-68* is/are pending in the application.

4a) Of the above claim(s) *36-44,57,58,60,61,64 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 8-35, 45-50, 55, 56, 59, 63 and 66-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of response to restriction requirement and remarks filed 5/30/07; receipt of request for continued examination, amendment and remarks, all filed 1/24/07. New claims 66-68 are added. Claims 2, 51 and 62 are canceled. Claims 1, 3, 4, 8-38, 41, 42, 44-50, 55, 57-59 and 63-65 are amended. Claims 1, 3, 4, 8-50, 55-61 and 63-68 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/07 has been entered.

Election/Restrictions

Applicant has elected with traverse the invention of group I, claims 1, 3, 4, 8-34, 45-50, 55, 56, 59, 63 and 66-68, with the comments that a) inventions I and III related as product and process of using the product and b) inventions I and II are not related as product and process of making the product, but, rather, are related as product and process of using the invention I because invention II requires contacting the product of invention I with water to form the aqueous composition. Applicant therefore, requests the rejoining of the product and process of using claims upon finding invention I allowable. Examiner would consider the merits of

rejoining invention II with I when allowable subject matter is found. The same is also true for invention III.

To this end, it is brought to applicant's attention that, in order to expedite prosecution in rejoining invention III with invention I, it is suggested that claims 41 and 42 be amended to recite the conditions that are treated with the modafinil composition in place of the "disease or disorder" now recited in lines 1 of the claims 41 and 42 since modafinil does not treat all diseases and disorders. That is, the limitations of claim 44 may be moved into claims 41 and 42.

Claim 35 was inadvertently omitted, claim 35 is included in group I and examined with claims 1, 3, 4, 8-34, 45-50, 55, 56, 59, 63 and 66-68. Therefore, claims 1, 3, 4, 8-35, 45-50, 55, 56, 59, 63 and 66-68 are examined. Claims 36-44, 57, 58, 60, 61, 64 and 65 are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 4, 11, 14, 15, 32, 33, 45-47 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nguyen et al. (US 5,843,347).

Nguyen teaches a pharmaceutical composition comprising particles or microparticles of active ingredient, physiologically acceptable hydrophilic excipient and water (abstract). The hydrophilic excipient comprises a polymer component and a water-soluble or water dispersible

component that acts as a diluent (column 6, lines 1-5). The polymer component is selected from the group consisting of gum Arabic, xanthan gum, gum tragacanth, alginates, pectinates, polyvinylpyrrolidone, polyethylene glycols, cellulose, carboxymethyl cellulose, cellulose ethers, carboxymethyl chitin, dextran, chitosan, gelatin, acrylic and methacrylic polymers and copolymers, colloidal silica and mixtures thereof (column 6, lines 11-23). The water-soluble or water dispersible component is selected from the group consisting of lactose, glycocoll, mnnnitol, glucose, sucrose, maltodextrin, cyclodextrins and derivatives thereof (column 6, lines 44-49). The hydrophilic excipients can also comprise surfactants that are capable of oral administration and the surfactants can be polysorbates, sorbitan esters, fatty glyceride polyethers, lecithins, sodium lauryl sulfate, sodium dioctylsulfosuccinate and mixtures thereof (column 7, lines 2-7). The process of preparing the modafinil particles involves homogenization of the active ingredient in solution, suspension, or emulsion and freeze-drying or lyophilization (column 8, lines 15-24). The active ingredient is selected from the group consisting of paracetamol, probucol, piroxicam, phloroglucinol, tiadenol, flerobuterol, modafinil, dexfenfluramine, carbinoxamine maleate, loperamide, lorazepam and mixtures thereof (claim 13). Claims 45-47 recite the properties of the composition. Oral administration is route of administration and route of administration of a composition is does not patentably distinguish the claimed composition over the prior art.

The preparation is lyophilized such that the amount of water is driven to a minimum and would be less than 10%. Therefore, in the alternative, the modafinil composition of Nguyen is non-aqueous as gleaned from applicant's specification at paragraph [0020].

Response to Arguments

4. Applicant's arguments filed 1/24/07 have been fully considered but they are not persuasive.

Applicant argues that Nguyen fails to disclose non-aqueous liquid or solid solution.

Response:

The preparation of Nguyen is dried and when dried would contain water in amount that is less than 10%. The published specification at paragraph [0020] defines non-aqueous as one that contains from 0-10% water. Claim 1 is an aqueous solution without the specification for liquid or solid solution. The dried product meets the limitation of solid solution.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 8-10, 12, 13, 16, 17-31, 34, 35, 55, 56, 63, 66 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347

Nguyen is discussed above. Regarding the amounts of surfactant in claims 8, 9, 23-25, 27-30; and regarding the amount of modafinil in claims 17 and 18, it is within the purview of the artisan to use amounts of surfactants and modafinil in the composition to provide the desired composition. However, Nguyen is silent on the optical character of the modafinil. But it is known in the art that modafinil in the absence of designation of d- or l-, is the racemic form comprises of the l- or d- form. Therefore, it would have been obvious to use the either the d- or l- or the racemic form in the preparation. In the absence of factual evidence, the use of the specific l-form of the modafinil is not inventive over the use of the racemic form.

Response to Arguments

8. Applicant's arguments filed 1/24/07 have been fully considered but they are not persuasive.

Applicant argues that Nguyen fails to teach liquid or solid non-aqueous solution.

Response:

The preparation of Nguyen is dried and when dried would contain water in amount that is less than 10%. The published specification at paragraph [0020] defines non-aqueous as one that contains from 0-10% water. Claim 1 is an aqueous solution without the specification for liquid or solid solution. The dried product meets the limitation of solid solution.

9. Claims 47-50 and 55, 56, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Grebow et al. (US 5,618,845).

Nguyen is described above as containing modafinil and surfactant and solvent. Nguyen's composition is not encapsulated.

Grebow teaches a pharmaceutical composition comprising modafinil particles or modafinil pharmaceutically acceptable salt particles (abstract, column 2, column 3, lines 1-55 and claims 1 and 2) and non-toxic pharmaceutically acceptable carrier (column 4, lines 4-1%. Grebow's composition contains an appropriate dosage of between 50 mg and 700 mg of modafinil with a preferred amount of 400 mg (column 4, lines 1 1-18 and column 10, lines 15-17). The modafinil pharmaceutical composition is administered as a tablet, capsule, powder, pill, liquid, suspension or emulsion; the modafinil composition can also be administered topically via epidermal patch or administered via direct injection (column 10, lines 18-26). Grebow further teaches a method of altering somnolent state, for example, narcolepsy, idiopathic hypersomnia and related sleep disorders by administering to a mammal a pharmaceutical composition comprising an effective amount of modafinil particles; and an effective amount of the pharmaceutical composition is defined as an amount effective for treating the somnolent state (column 3, lines 56-67). In human clinical trials, modafinil is administered to physically and mentally healthy male subjects (column 5, lines 46 to 56). Regarding claim 67, Grebow teaches liquid or suspension or emulsion composition of modafinil.

The composition of Grebow encompasses stable and unstable suspensions because the prior art does not exclude stable suspensions and thus the suspension of Grebow would be inherently stable. It is also noted that Grebow discloses suspensions containing modafinil and in

the suspension modafinil is not crystalline and the particles of modafinil are suspended in the solvent. The composition of Grebow can also be administered as a liquid as described above meeting claim 67

Grebow also teaches administering the prior art composition in clinical trials to mentally and physically healthy male subjects. Orally administering modafinil particles to human subjects (column 5, lines 46-56) would necessarily bring modafinil particles in contact with the aqueous environment in the human subject since human body is mostly water. the prior art is silent on the form of the capsule. Since the prior art is silent on the form of the capsule, hard or soft gelatin capsule, the prior art broad teaching of a capsule encompasses both soft gelatin capsule or hard capsule. The expected result would be the encapsulation of modafinil particle in soft or hard gelatin capsule meeting claims 48-50. Therefore, regarding soft or hard capsule, one of ordinary skill in the art is capable of encapsulating the composition in hard or soft in hard capsule or soft gelatin capsule. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to encapsulate the solid of Nguyen in the hard or soft capsule of Grebow for administration of modafinil.

Response to Arguments

10. Applicant's arguments filed 1/24/07 have been fully considered but they are not persuasive.

Applicant argues that Nguyen fails to teach liquid or solid non-aqueous solution.

Response:

The preparation of Nguyen is dried and when dried would contain water in amount that is less than 10%. The published specification at paragraph [0020] defines non-aqueous as one that

contains from 0-10% water. Claim 1 is an aqueous solution without the specification for liquid or solid solution. The dried product meets the limitation of solid solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600